

### **REMARKS**

Claims 1-14, 18, and 19 are pending in this application. No further amendments to the claims are made herein.

#### **Double Patenting**

Applicants respectfully request that the obviousness type double patenting rejection be held in abeyance until the claims are otherwise allowable. Additionally, due to the confusion earlier in the case and comments herein, which may equally apply to at least some of the double patenting rejections, Applicants respectfully request the Examiner to reconsider the double patenting rejections and set forth with specificity the current double patenting rejection, for clarity on the record.

#### **Claim Rejections 35 U.S.C. § 103**

Claims 1-4, 18 and 19 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over WO 99/03859 and WO00/42044. It is unclear from the rejection, but it appears that the rejection is based on the combination of the two references.

The Office appears to be relying on a theory of homology ("even if true 'homology' is not present").

The Federal Circuit, in Takeda, recently addressed obviousness based upon structural similarity, and found lack of obviousness despite structural similarity. The court noted the claimed compound differed from the prior art compound in two ways, an ethyl substituent rather than methyl, and the position of that ethyl on a ring (i.e. ring walking).

The court stressed that although "normally a prima facie case of obviousness is based upon structural similarity" (quoting In re Deuel), "in order to find a prima facie case of unpatentability in such instances, a showing that the 'prior art would have suggested making the

specific molecular modifications necessary to achieve the claimed invention' was also required."(Takeda, citations omitted.)

This requirement is consistent with the Supreme Court's KSR decision where the Court acknowledged the importance of identifying "a reason that would have prompted a person of ordinary skill in the relevant field to combine elements in the way the new claimed invention does." The Takeda court went on to say "in cases involving new chemic compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound."

Applicants respectfully assert that, as in Takeda, the Office has not identified any such reason.

In Takeda, the court found there was no evidence of a motivation to select the starting compound, compound b, from among the myriad of compounds disclosed in the prior art. Similarly, in this case, the Office has not pointed to any reason for selecting any of the handful of compounds the action points to from the myriad of compounds disclosed by WO '859 or for selecting the compound pointed to from the number of compounds disclosed in WO '044. Indeed, these compounds appear to have been singled out only with the benefit of Applicants' current application. Thus, it is unclear why one of skill in the art would choose these compounds to use as a basis for further modification.

Even if there were some basis to choose these compounds, there still is no evidence of "some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." The Takeda court, indicated the courts "found nothing in the prior art to suggest making the specific molecular modifications to [the starting compound] that are necessary to achieve the claimed compounds." After merely showing chemical structures from two reference patents, the Office presents only the naked conclusion that the disclosures "thus motivat[e] one of skill in the art to modify the

compounds to obtain similar homologues.” (A discussion of homology and “true homology” follows, but we do not believe it is germane to the current analysis.)

The Office has failed to provide any evidence of a reason why one of skill in the art would select any of the reference compounds to which modification could be made, or why one of skill in the art would make the modifications needed to reach the claimed compounds. Additionally, the Office has not presented any evidence that such changes, even when made, would be expected to have similar results.

For each of these reasons, Applicants respectfully submit that the Office has not established a prima facie case of obviousness. Accordingly, withdrawal of the rejection is respectfully requested.

The Commissioner is hereby authorized to charge any fee or underpayment thereof, including extension fees, or credit any overpayment to Deposit Account No. 26-0166.

Early reconsideration and allowance of all pending claims is respectfully requested. The examiner is requested to contact the undersigned attorney if an interview, telephonic or personal, would facilitate allowance of the claims.

Respectfully submitted,  
/Michael A. Patané/

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